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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,086	11/24/2003	Charles B. Chapman	100201800-1	7958

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INTELLECTUAL PROPERTY ADMINISTRATION
FORT COLLINS, CO 80527-2400

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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05/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/722,086

Applicant(s)

CHAPMAN, CHARLES B.

Examiner

Nathan A. Bowers

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 15-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding (US 20030199081) in view of Mowry (US 7078237) and/or Doung (US 20020177135).

With respect to claims 1, 5-11 and 12, Wilding discloses a disposable biochip comprising a substrate and a region on the substrate having components configured to interact with a biological substance. More specifically, Wilding discloses a PCR chamber (Figure 1:22) within which nucleic acid samples interact with reagents required for amplification. This is described in paragraph [0040] and [0044]. Paragraphs [0014] and [0045] indicate that the temperature of the PCR chamber is regulated by microprocessor controlled resistance heaters positioned in the substrate. These resistance heaters are configured to assist the reagent components in interacting with the nucleic acid samples. According to the protocol of PCR, the heaters move the temperature of the biochip through at least one heating cycle to amplify the DNA. Wilding, however, does not state that the heating devices are configured to generate heat sufficient to pyrolyze the nucleic acid sample following normal thermalcycling procedures.

Mowry discloses a biochip that comprises a substrate (Figure 1:120) and a heating device (Figure 1:110) integrated with the substrate in order to form a pyrolysis stage (Figure 2:100). This is described in column 4, lines 8-30. Column 6, lines 30-47 indicate that the heating device is configured to generate heat sufficient to pyrolyze a biological substance disposed within the biochip.

Doung discloses a disposable biochip capable of performing PCR and facilitating the detection of nucleic acid analytes through the use of hybridization arrays. Doung indicates that a plurality of heating means and thermocontrollers are utilized to regulate the temperature within reaction chambers during amplification and detection processes. In paragraph [0326], Doung teaches that it is known in the art to use heating means disposed upon a biochip to create extreme temperatures over a sufficient period of time sufficient to kill and destroy a biological sample.

Wilding, Mowry and Doung are analogous art because they are from the same field of endeavor regarding biochips.

At the time of the invention, it would have been obvious to utilize the heating means disclosed by Wilding to generate extreme temperatures in order to pyrolyze biological substances following normal thermalcycling procedures. Mowry indicates in column 4, lines 8-30 that resistive heating elements, similar to those disclosed by Wilding, are capable of producing temperatures sufficient to pyrolyze a variety of biochemical compounds. Doung teaches in paragraph [0326] that it is beneficial to destroy biological samples via heat treatment after analysis because many samples are dangerous and would pose health problems to operators if contacted.

With respect to claims 2 and 13, Wilding and Mowry/Doung disclose the apparatus and method set forth in claims 1 and 9 as set forth in the 35 U.S.C. 103 rejection above. Although not expressly disclosed, it can be inferred that the decontamination procedures taught by Mowry and Doung rid the biochip substantially free of contaminants.

With respect to claims 3 and 14, Wilding and Mowry/Doung disclose the apparatus and method set forth in claims 1 and 9 as set forth in the 35 U.S.C. 103 rejection above. Additionally, Wilding discloses in paragraph [0008] that the disclosed apparatus is intended to conduct clinical tests for paternity and genetic and infectious diseases. These tests (clearly paternity testing) use biological substances obtained from a human source. Doung also discloses the use of assays that utilize biological substances from a human source.

With respect to claim 4, Wilding and Mowry/Doung disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Wilding additionally indicates in paragraphs [0051]-[0057] that the heating device is in communication with a variety of bio-analysis devices capable of detecting the PCR product.

Response to Arguments

Applicant's arguments filed 05 March 2007 with respect to the 35 U.S.C. 102 rejections involving Mowry have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 05 March 2007 with respect to the 35 U.S.C. 103 rejections involving the combination of Wilding with Mowry and/or Doung have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Wilding teaches away from the use of heat that would cause pyrolyzation. Wilding relies on a heat and cooling cycle to amplify nucleotides in a PCR process. It is submitted that the addition of a pyrolyzing heat to such a system would destroy the functionality of Wilding.

In response to Applicant's arguments, please consider the following comments.

It is agreed that the addition of pyrolyzing heat to the Wilding system during PCR would destroy the functionality of the disclosed system. However, this is not what the current rejection is suggesting. In light of the Mowry and Doung references, one of ordinary skill in the art would be motivated to apply excessive heat *after* the completion of the assay and *after* the critical

components have been removed from the substrate. This is what is suggested by Doung in paragraph [0326], not sterilization during PCR. Doung clearly teaches that pyrolyzing procedures are beneficial because they facilitate in the disposal of material *following the completion* of the assay. Wilding and Doung are similar references in that both disclose the use of substrates to accommodate biochemical analytical procedures such as PCR. Since Doung does not disclose the application of temperatures sufficient to pyrolyze substances during the assay, one of ordinary skill in the art would have no reason to apply these severe temperatures to the Wilding system during the assay, either.

(b) There is no motivation to combine Wilding with Mowry and/or Doung.

In response to Applicant's arguments, please consider the following comments.

The Examiner disagrees with this assertion, as Mowry and Doung each (especially Doung) provide motivation that would suggest to one of ordinary skill in the art to utilize the heating elements of Wilding to pyrolyze biological substances following the completion of the assay. Mowry indicates in column 4, lines 8-30 that resistive heating elements, similar to those disclosed by Wilding, are capable of producing temperatures sufficient to pyrolyze a variety of biochemical compounds. Doung teaches in paragraph [0326] that it is beneficial to destroy biological samples via heat treatment after analysis because many samples are dangerous and would pose health problems to operators if contacted.

(c) Even though Doung does disclose the use of a thermal controller for controlled heating, the thermal controller is not part of the biochip. Rather, it is an outside source that

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heats a cartridge containing a plurality of biochips. It is submitted that the combination would fail to produce the instant invention since the Applicant's claim set contains a disposable biochip having an integrated heating device.

In response to Applicant's arguments, please consider the following comments.

Both Wilding and Mowry disclose that it is known in the art to provide heating elements disposed directly on a supporting substrate. It is not suggested that the substrate of Wilding should be heated by an external heating source. Rather, one would have been motivated to use the existing heating elements of Wilding to create extreme temperatures following the completion of the assay in order to pyrolyze biological substance. Alternatively, one would have been motivated in light of Mowry to add extra heating elements to the substrate of Wilding if it was determined that Wilding's existing heat sources are incapable of creating the necessary temperatures.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

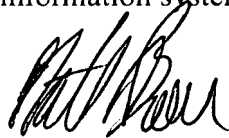
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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